

ABSTRACT

A method for identifying and assessing risks associated with a pharmaceutical product. The method comprises identifying adverse events caused by a pharmaceutical product, identifying the failure modes in the process of using said pharmaceutical product that exposes patients to said adverse events, quantifying the potential effects of said failure modes to conduct a hazard assessment for purposes of evaluating the need to mitigate the failure mode, and designing a risk management program to manage the adverse events. In addition, the present invention includes a method for creating effective interventions for use in mitigating the risk of the pharmaceutical product. Such method includes the creation of educational materials which are continually evaluated and revised to achieve an expected level of effectiveness on a target audience.